Advanced Circulatory Systems Inc.
ResQCPR System (P110024)

Proposed Post-Approval Study

The primary objective of the proposed post-approval study is to evaluate the introduction and implementation of the ResQCPR System into current EMS Systems that track their outcomes from out-of-hospital cardiac arrest. The proposed study design takes into account many of the lessons learned from the ResQTrial. The pivotal ResQTrial study was conducted in an emergency scenario and faced several challenges. There were limitations posed by the inability to gain prior informed consent, the transfer of patient care from a pre-hospital to a hospital setting, and the necessity of conducting neurologic exams at the primary and secondary endpoints. Further, there were many potentially confounding variables (e.g., time to treatment, other concurrent treatments, post-resuscitation care) that factored into the evaluation of the ResQCPR System. Although efforts were made to standardize these potentially confounding variables to the extent possible during conduct of the ResQTrial, replicating the design and conduct of the ResQTrial in a commercial post-approval study setting would be extremely difficult, if not impossible. This is especially so for any post-approval study design that would require obtaining informed consent of patients or next of kin for participation is such a study. The proposed post-approval study takes these considerations into account and at the same time provides a way to meaningfully meet reasonable study objectives.

The proposed post-approval ResQCPR System evaluation would be a registry-based, observational study of the clinical outcome data generated by real-world use of the device. At present, many EMS systems in the United States are participating in the Cardiac Arrest Registry to Enhance Survival (CARES), which allows for the tracking of sudden cardiac arrest outcomes through a secure, web-based data management system. CARES was developed in 2004 in collaboration between the Centers for Disease Control and Prevention (CDC) and Emory University to develop a registry that could help increase out-of-hospital cardiac arrest (OHCA) survival rates.

CARES currently tracks outcomes on a voluntary basis in over 400 EMS agencies in 26 states. Outcomes data includes the number of arrests in any given city or region, the age and gender of the patient, whether or not the arrest was witnessed, whether there was bystander CPR, the presenting heart rhythm, the location of the arrest, the time intervals from 911 call to various treatments, and in-hospital outcomes including hospital admission and discharge rates. CARES uses a HIPAA-compliant methodology to protect confidentiality. The company proposes to incorporate the use of the ResQCPR System into the data elements for CARES.

The Company proposes to track outcomes for the first 1,000 patients treated with the ResQCPR System in selected EMS systems after commercial launch. The purpose of the observational study would be to confirm that overall survival rates in the real world are consistent with survival rates obtained in the ResQTrial. Neurologic outcomes based upon the modified Rankin Scale score will not be tracked given the difficulty in consistently and accurately obtaining this information. The participating sites will include existing ResQTrial clinical sites and other clinical locations that already track survival to hospital discharge through the CARES program. EMS personnel in these sites will be trained in a manner similar to the approach used in the ResQTrial, including written and video course material, hands-on training, and retraining 3 months and 9 months after launch of the study.

The Company anticipates this proposed observational study will demonstrate that the effectiveness of the ResQCPR System is similar between the pivotal ResQTrial study and the real-world registry outcomes.